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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,780	05/03/2002	Yoshio Okubo	SDF-02-8	5042
31764	7590	11/05/2003	EXAMINER	
LAW OFFICE OF STUART D. FRENKEL, P.C. 3975 UNIVERSITY DR., STE. 330 FAIRFAX, VA 22030			YOUNG, MICAH PAUL	
		ART UNIT		PAPER NUMBER
		1615		
DATE MAILED: 11/05/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/069,780	OKUBO ET AL.
Examiner	Art Unit	
Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on \_\_\_\_ .

2a)  This action is **FINAL**.                  2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-8 is/are pending in the application.  
    4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-8 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## **Application Papers**

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .  
4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-3, and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Saferstein et al (USPN 6,086,856 hereafter referred to as ‘856). The claims are drawn to an oral formulation comprising a medicament and a foaming agent. The claims also recite a method of administration.

‘856 discloses a system for delivering a foaming oral composition. The foaming composition is delivered via an air driven foaming device (claims) container and comprises among other foaming compositions polyethylene glycol, polysorbate and sodium lauryl sulfate (col. 7, lin. 1-col. 9, lin. 34). These disclosures render the claims anticipated.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Mackles et al (WO 86/05392 hereafter referred to as ‘05392). The claims are drawn to an oral formulation comprising a medicament and a foaming agent. Claims 5 and 6 are drawn to a method of administration comprising ejecting the formulation and forming a foam.

‘05392 discloses a aerosol foaming composition comprising medicaments and foaming agents. The foaming agents are selected from threes classes: glycerol esters, polyglycerol esters and sorbitan ester (pg 8- pg 10, lin. 3). Since the formulation is in aerosol form, the composition

further comprises propellants and is administered via an aerosol container (pg. 10, lin. 20 – pg. 14, lin. 23). These disclosures render the claims anticipated.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saferstein et al (USPN 6,086,856 hereafter referred to as ‘856). The claims are drawn to an oral foaming formulation comprising a mixture of foaming agents.

As disclosed above ‘856 discloses an oral foaming composition comprising polyethylene glycol, polysorbate and sodium lauryl sulfate. The reference however does not disclose the exact mixtures of claims 4 and 8. However the reference discloses a mixture of sodium lauryl sulfate and polysorbate in one formulation (example 3).

It is the position of the examiner that such combination as recited in claims 4 and 8 would be well within the level of skill in the art. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

With these things in mind one of ordinary skill in the art would have been motivated to combine the foaming agents disclosed by '856 in order to impart stability ensure proper delivery of the active agents. It would have been obvious to combine the foaming agents in such a way with an expected result of a foaming oral composition capable of delivering hygienic agents to the mouth.

#### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Manoussos et al (USPN 3,887,703), Vermeer (USPN 5,624,906) and Quast (USPN 5,736,158) all disclose oral foaming composition comprising foaming agents and medicaments

#### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young  
Examiner  
Art Unit 1615

MP Young

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600